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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/598,982	06/21/2000	Mark Maffitt	34506.104	6761

7590 05/22/2002

Joseph T Leone
Dewitt Ross & Stevens S C
Firstar Financial Centre
8000 Excelsior Drive Suite 401
Madison, WI 53717-1914

EXAMINER
RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
1652	9

DATE MAILED: 05/22/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

BS

Office Action Summary	Application No. 09/598,982	Applicant(s) MAFFITT ET AL.	
	Examiner Delia M. Ramirez	Art Unit 1652	

-- Th MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) *26-33,38-40,46-53 and 59-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25,34-37,41-45,54-58* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Claims 1-61 are pending.

Applicants' election with traverse of Group I, claims 1-25, 34-37, 41-45, 54-58, drawn to DNA constructs, host cells encoding and expression of recombinant human tryptases in Paper No. 8, filed on 2/21/2002 is acknowledged.

Applicant's traverse is on the ground(s) that the Examiner has not provided reasons and/or examples to support any of the conclusions of patentable distinctness between the restricted claims. In particular, Applicants argue that the Examiner has not provided indication as to the feasibility of using the different products as described in the previous office action Paper No. 6, mailed on 9/21/2002. Accordingly, Applicants assert, the Office has not carried the burden of providing technologically sound reasons or examples for concluding that each of Groups I-V are patentably distinct.

Applicant's arguments have been fully considered but are not deemed persuasive. Each one of the uses provided for the different inventions of the instant application are well known in the art. While the MPEP indicates that examiners must provide reasons and/or examples to support conclusions, the Examiner is not required to submit complete experimental protocols describing in great detail how one can use Applicant's invention in each specific example. To the best of the Examiner's knowledge, one of skill in the art would recognize that DNA can be used as a hybridization probe or in gene therapy and proteins can be used as therapeutics or in diagnostic methods. In addition, one of skill in the art would recognize that proteins do not

necessarily have to be made recombinantly using the DNA encoding them but they can be isolated from natural sources or prepared by chemical synthesis.

In regard to Groups III and IV, while one could argue that the antibodies of Group III can be used in the screening method of Group IV, even though this use is not stated in the claims, the restriction between Groups III and IV would still be proper since Groups III and IV would then be related as product and process of use. In that situation, the inventions can be shown to be distinct if it can be shown that (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The antibody of Group III can be used in the method of Group IV and in the purification of the protein of Group II by affinity chromatography.

In regard to Groups I and IV, the restriction is also proper because the DNA of Group I is not needed to practice the screening method of Group IV but the protein is. Recombinant expression of the DNA encoding the protein can be used to produce the protein but as indicated previously, the protein can be isolated from other sources or chemically synthesized.

In regard to Groups IV and V, it is not clear to the Examiner how Groups IV and V are related. Group IV is drawn to a method of screening a library with recombinant human tryptases. Group V is drawn to a method for modeling recombinant human tryptases. No obvious relationship can be found. In addition, Applicants have not provided any indication that would support the argument that these inventions are related either.

With respect to Groups II and V, as understood in the art, modeling of how a protein works requires the collection of experimental data which, when analyzed, would give some

indication as to how protein structure relates to function. While one could argue that the protein is required to obtained the experimental data which would lead to the modeling of the protein, the restriction between Groups II and V is still proper since Groups II and V would then be related as product and process of use. In that situation, the inventions can be shown to be distinct if it can be shown that (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). The protein of Group II can be used in the method of Group V, to make the antibodies of Group III, and in the screening method of Group IV.

The requirement, as it pertains to Groups I-V, is deemed proper and therefore is made FINAL.

Claims 26-33, 38-40, 46-53, and 59-61 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Supplemental Restriction Requirement

The instant Office Action is a supplemental restriction requirement. The previous Office action (Paper No. 6, mailed 9/21/2001) was a restriction requirement of pending Claims 1-61. This supplemental requirement is at the discretion of the examiner (see MPEP 802 and 37 CFR 1.142) and is deemed appropriate and necessary in view of the plurality of claimed patentably distinct inventions.

In addition to Groups I-V, some of the claims within these groups read on patentably distinct inventions drawn to multiple polynucleotide/polypeptide sequences, therefore each one

of these Groups is further restricted to one particular sequence (polynucleotide or polypeptide). Each of these polynucleotides/polypeptides represent an independent and patentably distinct invention due to their different structure, function, and sequence. Each sequence represents a different molecule therefore subject to a restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141. Furthermore, it would be unduly burdensome to examine more than one sequence (polypeptide or polynucleotide) because the search is not co-extensive or even overlapping. To do a comprehensive search, each one of the sequences must be searched individually. Therefore, examination of more than one polypeptide/polynucleotide sequence in each Group would present a burden on the Office.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement can be traversed (37 CFR 1.143). In the instant case, since Applicants have previously elected with traverse the generic Group I (DNA, host cells, vectors, and expression of DNA encoding human tryptases), a single polynucleotide sequence must be elected in response to this action.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
May 16, 2002

PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600